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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,110	12/27/1999	HERBERT E. SCHWARTZ	FZIO01000US4	8339

23910 7590 07/02/2003

FLIESLER DUBB MEYER & LOVEJOY, LLP  
FOUR EMBARCADERO CENTER  
SUITE 400  
SAN FRANCISCO, CA 94111

EXAMINER
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OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/02/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/472,110

Applicant(s)

SCHWARTZ ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Response to Arguments***

The following is in response to the amendment filed 4/28/03:

An action on the merits of claims 1-29 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Claim Rejections - 35 U.S.C. § 102**

The rejection of Claims 1 and 18-20 under 35 U.S.C. 102(b) is withdrawn in view of applicant's arguments.

**Claim Rejections - 35 U.S.C. § 103**

Applicant's arguments filed 4/28/03 have been fully considered but they are not persuasive. The rejection of Claims 1-29 under 35 U.S.C. 103(a) as being obvious over Tapolsky et al., U.S. Patent No. 5,800,832 in combination with Jacob et al., U.S. 5,985,312 is maintained for the reasons of record.

Claim 1-17 and 28 are drawn to an ionically cross-linked gel comprising a polyacid - carboxymethylcellulose, carboxyethyl cellulose; a polyalkylene oxide- in the form of polypropylene oxide, polyethylene glycol, polyethylene oxide and a multivalent cation – in the form of a divalent cation.

Claims 18 – 23 are drawn to the composition of claim 1, wherein the multivalent cation is a divalent cation accompanied by an inorganic or organic anion.

Claims 24 and 25 are drawn to the composition of claim 1 wherein the pH is in the range of about 2.0 to about 7.5.

Claims 26 – 28 are drawn to the composition of claim 1 further comprising an antithrombogenic drug.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Tapolsky teaches a polymeric composition comprising carboxypolysaccharides such as carboxymethyl cellulose, hydroxyethylcellulose etc., and polyalkylene oxides such as polyethylene oxide (col. 6, lines 23-67), wherein the polyacid and polyalkylene compositions may comprise from 5% - 95% by weight and have molecular weights comprising 5kd to 700 kd for the polyalkylene and 5kd to 150 kd for the polyalkylene oxide (col.5, line 55 – col. 6, line 32). Tapolsky also teaches the addition of antithrombogenic agents such as salicylic acid and ibuprofen, col. 7, lines 18 and 60) however Tapolsky does not teach the addition of a multivalent/divalent cation.

Jacob teaches that the addition of multivalent metal compounds, i.e.  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{Fe}^{2+,3+}$ ,  $\text{Al}^{3+}$  to polymer compositions containing polyacids and polyalkylene oxides improves the bioadhesive properties of these compositions (col. 5, line 57 – col. 6, line 62) which adequately bridges the nexus between the prior art and the invention as claimed.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to incorporate a multivalent/divalent cation to a polyacid/polyalkylene composition.

A person of ordinary skill in the art would have been motivated to incorporate a multivalent/divalent cation to a polyacid/polyalkylene composition given the use of these multivalent cations to improve the bioadhesive properties of polyacid/polyalkylene compositions in the prior art.

Applicant's primary argument is that the metal compounds disclosed in Jacob are not equivalent to the metals claimed by applicant. Applicant's recitation of a dictionary definition of metal compounds is moot given that one of skill in the art need only

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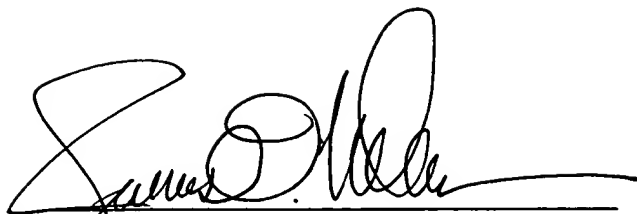
reference the teachings disclosed in Jacob for the definition. As such, Jacob clearly sets forth divalent and trivalent (which clearly indicate to one of skill in the art "multivalent) metal compositions (col.5, lines 63-65) in conjunction with the polyacids and polyalkylene oxides. The claims are drawn to a polyacid composition containing a "divalent or multivalent cation", there is no specific form set forth in the claim wherein applicant can claim that the divalent and multivalent cations set forth in Jacob is not probative. Not only does Jacob disclose analogous valence metal compositions, Jacob provides sufficient motivation with the teaching of improved bioadhesive properties, which is a purported benefit of applicant's claimed composition (as cited on p.5, line 28 of the specification....."Another object of the invention is to provide gel compositions having improved viscoelastic.....tissue adherence....". Thus the prior art has taught the claimed composition as well as the purported benefit of this composition. For the reasons cited above, the 35 U.S.C. 103 rejection of record is maintained.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Howard V. Owens  
Patent Examiner  
Art Unit 1623

A handwritten signature in black ink, appearing to read 'James O. Wilson', written over a horizontal line.

James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

**JAMES O. WILSON**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**